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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,524	12/29/2003	Richard E. Parizek	I 1995.184 US D1	8568

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INTERVET INC.
PATENT DEPARTMENT
PO BOX 318
MILLSBORO, DE 19966-0318

EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/748,524	PARIZEK ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,15,17-19,40,46 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 15, 17-19, 40, 46 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 16, 2006 has been entered.

Amendment Entry

2. The amendment filed February 16, 2006 has been entered. Claims 1-3 and 40 have been amended. Claims 4-14, 16, 20-39 and 41-45 have been cancelled. Claims 1-3,15, 17-19, 40 and 46-47 are under consideration in this office action.

Withdrawal of Rejections

3. The following objections and rejections have been withdrawn in view of applicants' amendments and arguments:

a) the objection of claim 3; and

b) The rejection of claim 40 under 35 U.S.C. 112, second paragraph,

Response to Arguments

4. Applicant's arguments filed February 16, 2006 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. The rejection of claims 1-3,15, 17-19 and 40 under 35 U.S.C. 102(a) as being anticipated by Roberts (WO 94/22476) is maintained for reasons already of record. The rejection was on the grounds that Roberts teach a multicomponent vaccine for ruminants comprising an immunologically effective combination of a protective antigen component from at least six or seven specifically recited clostridial organisms, a protective antigen from at least one non-clostridial gram-negative *M. bovis and/or H. somnus*, and the specifically recited adjuvant wherein the dose is 2 ml or less.

Applicants' assert Roberts' examples are 5ml, and that *M. bovis* is merely mentioned in passing and no vaccine compositions are described specifically comprising *M. bovis.* Thus Roberts does not anticipate the instant claims. However it is the examiner's position a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). Furthermore, MPEP 2123 teaches that patents are relevant as prior art for all they contain, and that "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art,

relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968).

Here, Roberts may be relied upon because it reasonably suggest to one having ordinary skill in the art the administration of multicomponent vaccines in low dose volumes of about 2 ml or less. Roberts does not have to use each embodiment in an example to teach the effective dosage level. Furthermore, while applicants argue that Roberts does not teach examples comprising fewer than 5ml, however, applicant is reminded that applicants' own disclosure fails to show specific examples of a multicomponent clostridial vaccine comprising the non-clostridial *M .bovis* protective antigen wherein the vaccine is in a low dose volume of about 2 ml or less. Nor does applicants' specification show examples of a multicomponent clostridial vaccine comprising non-clostridial *M. bovis* and *H. somnus* protective antigens wherein the vaccine is in a low dose volume of about 2 ml or less. Rather applicants' specification merely mentions the possibility of having multicomponent clostridial vaccines combined with other antigens and mentions the possibility of having low dose volumed vaccines. Therefore applicants' argument is not persuasive.

MPEP 2131.03 states that when the prior art discloses a range which touches, overlaps or is within the claimed range, but no specific examples falling within the claimed range are disclosed, and the prior art discloses the claimed range with sufficient specificity, then the prior art anticipates the claims. Therefore, contrary to applicants' statements about Roberts broad teaching of low does volumes, Roberts clearly states

with sufficient specificity low dose multicomponent vaccines just as required by the instant claims. Therefore the disclosure of Roberts teaching a dosage of 1 to 5 ml and as low as 0.5ml would allow one of ordinary skill in the art to clearly envisage the instant claims range of about 2ml or less. Thus applicants' arguments are not persuasive.

Applicants' urge that because the claims no longer recite saponin as an adjuvant, Roberts no longer anticipates the claims. However it is the examiner's position that because the instant claims recite the use of an adjuvant which is an oil in water composition, a plant extract, or a liposomes, Roberts still anticipate the claims. Roberts teach that saponins are natural plant extract products, thereby meeting the plant extract limitation. Roberts even cites prior art references teaching that saponins are apart of oil –in- water composition and can be admixed in liposomes. Furthermore, Roberts teaches compositions using dispersible (non-depot) soluble adjuvants which include oil-in-water emulsions, cytokines, interleukins and interferons (page 6, lines 13-18). Therefore applicants' assertions are not persuasive and the rejection is maintained.

6. The rejection of claims 46-47 under 35 U.S.C. 102(a) as being anticipated by Roberts (WO 94/22476) is maintained for reasons already of record. The rejection was on the grounds that Roberts teach a method of immunizing a bovine animal comprising administering an effective amount of the vaccine in claims 1 or 2, just as instantly claimed. However, for the reasons set forth above, the rejection of claims 46 and 47 is maintained.

Claim Objections

7. Claims 46 and 47 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-3,15, 17-19, 40 and 46-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to a multicomponent vaccine for cattle comprising an immunogenically effective combination of a protective antigen from at least six or seven

clostridial organisms, a protective antigen component from at least one non-clostridial organism, which is *M. bovis* and at least one adjuvant selected from the recited group wherein the vaccine is in a low dose of about 2ml or less.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood,* 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.,* 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Furthermore, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.,* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe,* 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). *Regents of the University of California v. Eli Lilly & Co.,* 43 USPQ2d 1398.

The claims and specification recite a vaccine comprising at least six or seven of the recited clostridial organisms, including *C. chauvoei, C. septicum, C. novyi, C. perfringens type C, C. perfringens type D, C. haemolyticum, C. sordellii*, and *C. tetani*, however the specification provides no guidance as to what the upper limit of the number of clostridial organisms which may be encompassed by the vaccine. Moreover, the composition recites open language and therefore includes a wide variety and unlimited number of additional components. The claims fail to limit the number of clostridial organisms within the composition. No specific limitations for what additional clostridial organisms have been disclosed by the instant specification, and such unlimited additions have not taught and/or enabled by the specification.

Thus, the multicomponent vaccine for cattle comprising an immunogenically effective combination of a protective antigen from at least six or seven clostridial organisms, a protective antigen component from at least one non-clostridial organism, which is *M. bovis* and at least one adjuvant selected from the recited group wherein the

vaccine is in a low dose of about 2ml or less fail to meet the written description provision of 35 UCS 112, first paragraph. *Vas-Cath Inc. V. Mahurkar,* 19 USPQ2d 1111, make clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). There is no disclosure of vaccines comprising nine, ten or twenty clostridial organisms. Thus, the structure of the vaccine is not defined. Even though claims 3, 15,17-19 recite specific clostridial organisms, the claims do not limit the number of additional clostridial organisms that may be included in the vaccine. There is no written description of an immunogenic composition comprising additional clostridial organisms. Thus, a skilled artisan cannot envision the detailed structure of the vaccine since the specification has not defined what the additional clostridial organisms can be. Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method for production.

At best the specification and claims describe only the instantly recited clostridial organisms, however they fail to describe the upper limit on the number of clostridial organisms that may be comprised within the vaccine. The prior art teaches there are more than eight species of clostridial organisms, which include *C. acetobutylicum, C. beijerinckii, C. botulinum, C. butyricum, C. cellulolyticum, C. cellulovorans, C. difficile, C. histolyticum, C. kluyveri, C. sticklandii, C. symbiosum, C. tertium, C. tentani, C. tetanomorphum, C. thermocellum,* and *C. tyrobutyricum.* Moreover, there is no

disclosure of what other clostridial organisms may or may not be included within the instantly claimed vaccine or the upper limit of those clostridial organisms. The specification fails to teach the structure or relevant identifying characteristics of a representative number of vaccines sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed. Thus a skilled artisan cannot envision all the contemplated vaccines and therefore conception cannot be achieved until reduction to practice has occurred. It is noted however that applicants are not required to disclose every species encompassed by a genus. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In *Gostelli,* the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli,* 872 F.2d at 1012, 10 USPQ2d at 1618.

In view of the specification failure to disclose the identity or adequately describe a multicomponent vaccine for cattle comprising an immunogenically effective combination of a protective antigen from at least six or seven clostridial organisms, a protective antigen component from at least one non-clostridial organism, which is *M. bovis* and at least one adjuvant selected from the recited group wherein the vaccine is in a low dose of about 2ml or less, a skilled artisan would be required to de novo locate, identify and characterize the claimed vaccines. Therefore the full breadth of the claims fails to meet the written description provision of 35 USC 112, first paragraph.

8. Claims 46 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The preamble of the claims is drawn to a method of immunizing an animal, however the method recites administering the vaccine of claims 1and 2. The vaccines are for cattle and not all animals. Therefore the goal of the preamble is not commensurate with the steps of the method drawn to animals and not just cattle.

Conclusion

9. No claims allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
April 19, 2006

L. F. Smith
LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600